UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/636,801	08/10/00	MITCHAM J	210121.462C4

HM12/0406

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	7

DATE MAILED: 04/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/636,801	MITCHAM ET AL.	
	Examiner	Art Unit	
	Mary Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-72 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 9-12, 21, 23, 24, and 69-72 drawn to a polypeptide and pharmaceutical compositions, vaccines, and fusion proteins comprising said polypeptide, classified in class 530, subclass 350.

II. Claims 3-8, 13-16, 22, 25, 26, 68, drawn to polynucleotides and vaccines and pharmaceutical compositions comprising said polynucleotides, classified in class 536, subclass 23.1.

III. Claims 17, 63-67, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 29, 30 and 32, drawn to a composition of APC cells. Claim 32 will be examined only to the extent it reads on methods of administering APC's, classified in class 435, subclass 325.

V. Claims 33 and 34, drawn to compositions of T cells, classified in class 435, subclass 325.

VI. Claims 31 and 32, drawn to an anti-idiotypic antibody composition. If elected, claim 32 will be examined to the extent it reads on the administration of anti-idiotype antibodies, classified in class 424, subclass 131.1.

VII. Claims 49-56, drawn to detection methods comprising contacting a sample with an agent that binds a polypeptide, classified in class 435, subclass 7.1

VIII. Claims 57-62, drawn to a hybridization based method, classified in class 435, subclass 6.

IX. Claims 18-20, 27, 28, drawn to methods of treatment comprising administering polypeptides. Claims 18-20 and 27 of this group, if elected, will be examined to the extent they read upon administration of polypeptides, classified in class 514, subclass 2.

X. Claims 18-20, 27, drawn to methods of treatment comprising the administration of polynucleotides. This group, if elected, will be examined to the extent the claims read upon the administration of polynucleotides, classified in class 514, subclass 44.

XI. Claims 18-20, 28, drawn to methods of treatment comprising the administration of antibodies. This group, if elected, will be examined to the extent it reads on administration of antibodies, classified in class 424, subclass 130.1.

XII. Claims 35, and 36, drawn to methods of treatment comprising the administration of APC cells, classified in class 435, subclass 325.

XIII. Claims 35, 36 and 41-45, drawn to methods of treatment comprising the administration of T cells, classified in class 435, subclass 325.

XIV. Claim 36, drawn to method of treatment comprising administering an anti-idiotype antibody, classified in class 424, subclass 131.1.

XV. Claims 37-40, drawn to a method of expanding T cells, classified in class 435, subclass 2.

XVI. Claims 46-48, drawn to methods of identifying a tumor antigen, classified in class 435, subclass 7.9.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI are separate and distinct from one another, as they are each structurally and functionally different products, made by differing methods, having differing uses, and differing biological/ biochemical activities. As such, search and examination of all these separate products would pose an undue burden upon the examiner if not restricted.

The inventions of Groups VII-XVI are separate and distinct from one another, as each is a differing method, having differing objectives, method steps, parameters, and using differing reagents. As such, the search and examination of all these methods would pose an undue burden upon the examiner if not restricted.

Inventions I and each of IX and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in a completely separate method for purifying antibodies specific to that polypeptide.

Inventions II and each of VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used to express a polypeptide recombinantly.

Inventions III and each of VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in immunoaffinity purification, or immunohistochemistry.

Inventions IV and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the APC cells can be used in *in vitro* detection methods.

Inventions V and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T cells can be used in T cell activation assays *in vitro*.

Inventions VI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-idiotype antibodies can be used to purify relevant ligands *in vitro*.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected group drawn to an antibody, Applicants must elect a single specific antibody. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Under the present circumstances, it has been determined that the search and examination of more than one nucleic acid sequence would unduly burden the resources of the Office, and the examiner. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Due to the complexity of the restriction requirement, no telephone election was attempted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive communication will contain both the proper election of a group, and a further sequence election, as required. Applicant is requested to amend the elected claims to reflect this sequence election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

Mary K Zeman

MARY K. ZEMAN
PATENT EXAMINER
AU 1631

mkz
April 2, 2001